MAY 2 7 2005 K043198

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Heather Crawford, RAC
Director of Regulatory Affairs
863-683-8680 [voice]
863-683-8703 [facsimile]
hcrawford@safe-reuse.com [email]

Date

November 17, 2004

Device

- Trade Name: Vanguard Reprocessed Arthroscopic Wands
- Common Name: Reprocessed Arthroscopic wand or electrode
- Classification: 21 CFR, 878.4400
- Classification Name: Electrosurgical Cutting and Coagulation Device
- Device Class: Class II
- Product Code: GEI

Predicate Devices

Arthroscopic Wands legally marketed by the following original equipment manufacturers (OEM) and 3rd party reprocessor:

OEM / Reprocessor	Trade Name
ArthroCare®	ArthroWand®
Vanguard Medical Concepts, Inc.	Reprocessed Arthroscopic Wands

Indications for Use

When coupled with a compatible electrosurgical unit, an arthroscopic wand electrode is intended for resection, ablation and coagulation of soft tissues, and for hemostasis of blood vessels during arthroscopic procedures (of the knee, shoulder, ankle, elbow and wrist) that utilize a conductive irrigant.

Contra-indications

Use of this device is contraindicated for:

- non-arthroscopic surgical procedures
- arthroscopic procedures during which a conductive irrigant is not used
- patients for whom arthroscopic surgery is contraindicated
- patients with pacemakers or other electronic device implants

Continued on next page

014

K043198

510(k) Summary of Safety & Effectiveness

Device Description

The arthroscopic wand is a bipolar electrosurgical probe consisting of a shaft with an electrode array at its distal end and an integrated cable at its proximal end for coupling the electrode array to a high frequency power supply. The electrode array has at least one active electrode and one return electrode. Return electrodes are electrically insulated from the active ones and are spaced so as not to contact the tissue being treated. This spacing additionally insures that the electrical circuit is always completed by a surrounding conductive fluid and not simply arcing between electrodes. Depending upon OEM and clinical application, the electrode configuration can vary in number and spacing of electrodes, electrode material, or angle of the distal tip. "Suction wand" models have a small diameter tubing that originates in a cavity of the hub beneath the distal electrodes, runs through the interior of the device shaft and exits through the device handle to terminate with a standard pump connector. This lumen is intended for continuous aspiration in order to remove debris and cool the ablation site.

In use, the probe is positioned in close proximity to a target site within an electrically conducting liquid, such as isotonic saline. The conducting liquid provides a current path between the active electrode(s) and the return electrode(s). When RF voltage is applied between the active and return electrodes, high voltage gradients in the vicinity of the probe tip are generated. These voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The ablative process can be precisely controlled to remove a layer of tissue as thin as a few cells, without causing inadvertent injury to surrounding tissue. Formation of an ionized layer of plasma does not occur when the electrodes are activated with a lower voltage. Instead, electrical current passes through the tissue, creating a thermal zone for coagulation of blood vessels and shrinkage of some collagenous tissues of the joints during arthroscopic surgery.

Vanguard Reprocessed Arthroscopic Wands are previously used devices that have been cleaned, inspected, tested, packaged, and sterilized by Vanguard Medical Concepts, Inc.

Technological Characteristics

Vanguard Reprocessed Arthroscopic Wands are essentially identical to the Original Equipment Manufacturer (OEM) devices. No changes are made to the currently marketed OEM device's specifications (except for the insulation material) and the reprocessed Arthroscopic Wands possess identical technological characteristics.

Continued on next page

510(k) Summary of Safety & Effectiveness

K043198

Test Data	Cleaning, sterilization, packaging validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed Arthroscopic Wands are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.

01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Ms. Heather Crawford, RAC
Director of Regulatory Affairs
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K043198
Trade/Device Name: Vanguard Reprocessed Arthroscopic Wands
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 17, 2004
Received: November 18, 2004

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043198

Device Name: Vanguard Reprocessed Arthroscopic Wands

Indications for Use:

When coupled with a compatible electrosurgical unit, an arthroscopic wand electrode is intended for resection, ablation, and coagulation of soft tissues, and for hemostasis of blood vessels during arthroscopic procedures (of the knee, shoulder, ankle, elbow, and wrist) that utilize a conductive irrigant.

Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043198